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14. ABSTRACT
The U.S. military is providing amputees with state-of-the-art prosthetic devices. In addition to walking and changing direction, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. The largest problem for a lower extremity amputee is falls. Falling history and balance confidence are associated with reduced mobility capability and social activity. The goal of this research effort is to rehabilitate individuals with lower extremity amputations to reduce falls using a novel training method. The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 2-week period. Trunk motion and velocity was assessed using a perturbation test in an immersive virtual environment, since trunk kinematics has been shown to determine fall likelihood. We have enrolled 14 research subjects at the Naval Medical Center San Diego. Mean trunk flexion angle and velocity significantly improved after participating in the training program. The improved performance was maintained up to 6 months. Subjects reported decreased uncontrolled and semi-controlled falls in their free-living environment outside of the research laboratory. These results indicate that task-specific training is an effective rehabilitation method to reduce falls in persons with lower limb amputations.

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Introduction

The US global war on terrorism has resulted in many US warfighters sustaining extremity injuries. The US military is currently fitting amputees with state-of-the-art prosthetic devices. While amputees may try to focus on the advanced technology to try to solve some of the adjustment issues, “high tech” does not always equate to “high function”. In addition to walking and changing direction on a variety of surfaces, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. The key factor that limits the ability of amputees to achieve maximum functional capabilities is falls. Among individuals with a lower extremity amputation, 52% reported having fallen in the last 12 months, 49% reported being fearful of falling, and 65% have low balance confidence scores. Falls in warfighters with a lower extremity amputation can have serious consequences, including loss of confidence, fear of falling, and injury. As a result, those individuals with limited balance and stability are at risk for diminished quality of life. The goal of this research effort is to rehabilitate warfighters with a lower extremity amputation to increase trust in their prosthesis and reduce falls by using a novel training method. Deliverables include a quantitatively derived, deployment ready, advanced gait rehabilitation system and method that can improve functional outcome and/or shorten the time required for injured service men and women to return to active duty or to a productive civilian life.

Body

This was the second year of a research effort to develop and test a novel training technique aimed at increasing and/or accelerating the functional capabilities of warfighters with a lower extremity amputation and enhancing their return to active duty or a productive civilian life. Our efforts have focused on enrollment and training.

Fourteen subjects (12 transtibial and 2 transfemoral) have been enrolled. The protocol calls for subject functional capabilities to be collected at four time points. Subjects are tested before starting the training protocol to establish their baseline capabilities. The subsequent training consists of 6 training sessions over a 2-week timeframe. The subjects are tested again following completion of the training. To evaluate the extent to which the training is maintained, all subjects are assessed for functional outcomes at 3 and 6 month time points following completion of the training. Twelve subjects have completed the training, as well as the 3 and 6 month follow-up evaluations. One subject dropped out due to non-protocol related issues. One subject who required additional surgery plans to return to the protocol once he is medically cleared to do so.

Active recruitment for the project is ongoing. There are subjects in the pipeline ready to enroll as soon as they meet the functional level requirements. Specifically, one transtibial amputee in San Diego is being enrolled now. Three transtibial amputees in rehab at NMCSD will be enrolled when they meet the requirements for enrollment. Two transfemoral amputees have expressed interest. One is waiting to meet the inclusion criteria and one is waiting to have his microprocessor knee reprogrammed before beginning the testing. Contacts have been established with the local VA for identification of subjects. In addition, the IRB protocol has been modified and approved to reach out to subjects residing in the San Diego catchment area who were rehabilitated at Walter Reed/Bethesda or the Center for the Intrepid.

The fall prevention training program utilizes an Active-Step treadmill (Simbex, Lebanon, NH). This microprocessor-controlled treadmill is designed to deliver task specific training perturbations. Three types of perturbations are used during six, 30 minute training sessions conducted over a 2-week period. During each training session, the task difficulty is increased as the patient’s ability progresses. Three types of perturbations are delivered to subjects. Two “static” and one “dynamic” perturbations

are used: (1) *static step*: the belt is moved while the patient is standing still and the patient responds with one forward step; 2) *static walk*: the belt is moved while the patient is standing still and the patient must respond with multiple forward steps: and 3) *eTRIP*: while the subject is walking on the treadmill the perturbation is delivered at a random time and the subject must respond with multiple forward steps.

Assessment of the training program effectiveness is done using a perturbation testing protocol in a Computer Assisted Rehabilitation Environment (CAREN, Motek Medical, Amsterdam). This fully immersive virtual environment contains a 6 degree-of-freedom motion platform containing an instrumented dual belt treadmill with integrated force plates. The platform is surrounded by a 180 degree screen. During the testing protocol perturbations simulating a trip in the natural environment are delivered. Six perturbations (3 left limb/3 right limb) are delivered in a randomized manner while the subject walks for five to six minutes at a velocity standardized to leg length. A pre-test and post-test assessment of the rehabilitative program is performed. The key outcome variables are peak trunk flexion and trunk velocity between time of perturbation and recovery step completion. These variables have been shown to determine the likelihood of a fall.

Patient centered information is also collected prior to and at the conclusion of the training using several questionnaires. The Prosthesis Evaluation Questionnaire (PEQ-A) is used to quantify patient satisfaction. For the PEQ-A, an uncontrolled fall is defined as a sudden loss of balance without any time to protect against a fall. A semi-controlled fall is defined as a loss of balance with awareness that a fall is occurring so that there is the opportunity to brace for the fall or catch something in order to not get hurt and land in a protected fashion. The Activity-Specific Balance Confidence Scale (ABC) is used to assess the subject's perceived balance confidence.

The research program had 4 tasks. The results will be presented for each task.

Task 1: *Conduct installation and training at the Naval Medical Center, San Diego*

COMPLETED

Task 2: *Assess functional performance improvements in amputees using the treadmill training system*

The training program has been beneficial. All study subjects can be considered high functioning based on their baseline ABC questionnaire scores (90 $\pm$ 8). Nonetheless, there was a significant decrease pre- to post- training for mean peak trunk flexion angle ($p<0.001$) and velocity ($p<0.001$) at the time of the recovery step (Figure 1). Perturbations of the sound (non-prosthetic) limb exhibited significantly greater mean peak trunk flexion velocity ($p=0.01$) when compared to perturbations of the prosthetic limb. There was no significant side-to-side difference in mean peak trunk flexion angle ($p=0.10$).

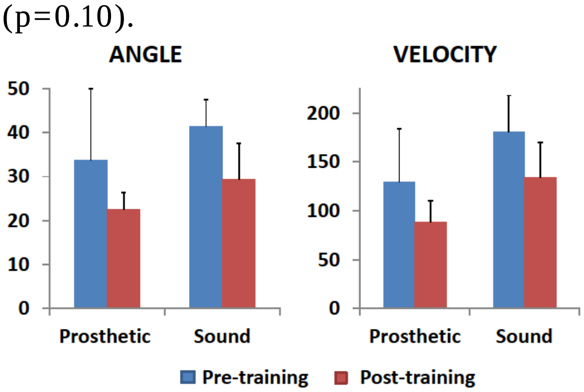

Figure 1: Trunk flexion angle (degrees) and velocity (deg/sec) before and after training when the subjects were subjected to gait perturbations while on the prosthetic and sound limb. There were statistically significant changes in trunk kinematics angle. Perturbations of the sound limb resulted in significantly greater changes. The data demonstrated a clinically significant improvement in ability to recover from a postural perturbation and avoid falling.

Task 3: *Evaluate the ability of the treadmill system to achieve rapid rehabilitation of amputees*

Comparisons were also made between patients who had not been enrolled in the research study to patients who had participated in the training. These control subjects were selected from patients who had previously been studied in the Gait Laboratory at the Naval Medical Center-San Diego. Patients were matched based on age, BMI, residual limb length and amount of time they had been walking without an assistive device. There were no significant differences between the subject enrolled in the study and the control group. Both groups were studied at two time points which were spaced 3 months apart. The only difference is that the control group did not receive the novel fall-prevention training. Notably, there were significant differences in gait parameters between the trained group at three months following training and the second study of the control group. The trained subjects demonstrated a significant increase ($p=0.057$) in walking velocity (Figure 2) which was due to significant increases in step length ($p=0.009$) of the prosthetic leg and stride length ($p=0.02$) (Figure 3).

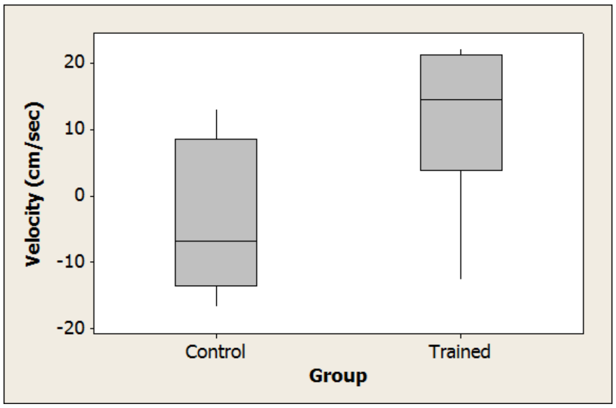

Figure 2. Changes in walking speed over a 3 month period for the control group and the group receiving the novel rehabilitation (trained group). Changes that are greater than zero indicate an increase in walking speed. The trained group walked significantly faster after receiving the training.

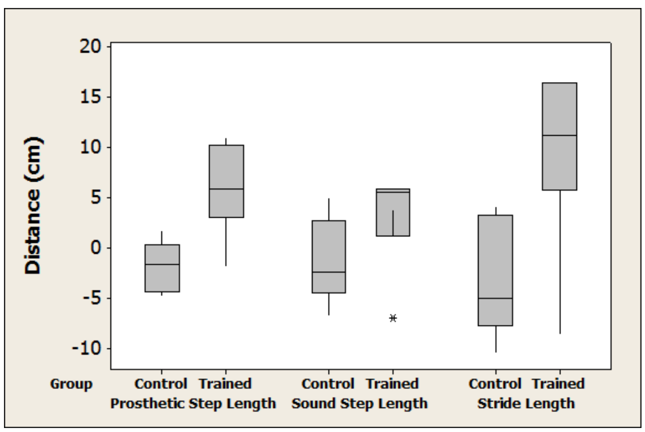

Figure 3. Changes in step length and stride length over a 3 month period for the control group and the group receiving the novel rehabilitation (trained group). Changes greater than zero indicate an improvement. The trained group had clinically meaningful improvements in their stride characteristics.

Task 4: *Evaluate motor skill retention following completion of rehabilitation training*

Importantly, the skills acquired were retained at 3 and 6 months after training (Figure 4). There were no significant changes in the mean peak trunk flexion angle (p=0.12) or mean peak trunk flexion velocity (p=0.22) over time. Perturbations delivered to the sound (non-prosthetic) side resulted in higher trunk flexion velocities than when perturbations were delivered to the prosthetic side (p=0.05). The PEQ questionnaire responses indicate increased confidence in the ability to recover from a trip in the community. All subjects reported that the number of uncontrolled falls were zero after training. Further, most (5/8) of the subjects indicated that the number of semi-controlled falls had been reduced to zero following training, one subject reported that the number had been reduced, and two subjects did not demonstrate any trends in the data.

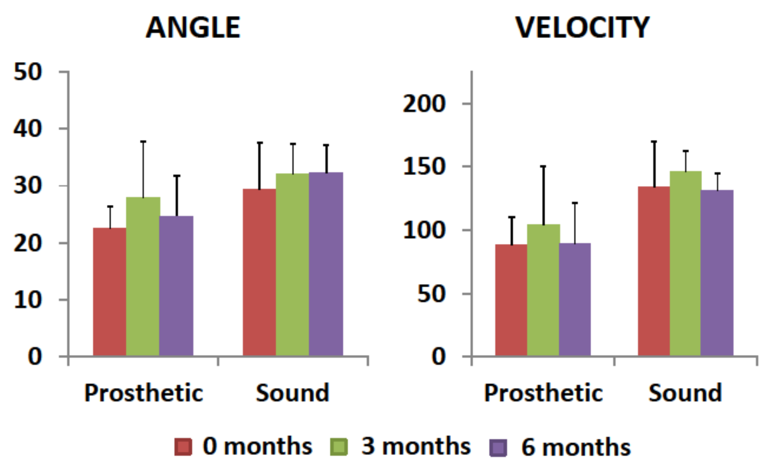

Figure 4: Trunk flexion angle (degrees) and velocity (deg/sec) over time following completion of the training. There were no significant changes in trunk kinematics. Perturbations delivered to the sound side resulted in significantly higher trunk velocities than when these same disturbances were delivered to the prosthetic side. The data demonstrates that the subjects are able to retain the training effect up to six months after completing the training.

Key Research Accomplishments

- 14 subjects enrolled and trained
- Training is accomplished in six, 30 minute sessions conducted over a 2 week period
- Data demonstrates improvements in ability of transtibial amputees to avoid a fall following large postural perturbations
- Military personnel undergoing the novel rehabilitation training are showing greater improvements in their gait over a shorter time-frame.
- Critical training effects are retained for at least 6 months following completion of the training
- Amputees report reduction in falls in their free-living environment

Reportable Outcomes

- Abstracts on the research program have been presented at
    - Military Health System Research Symposium, Ft. Lauderdale, FL, August 6-9, 2012
    - European Society of Movement Analysis for Adults and Children, Stockholm, Sweden, September 12-15, 2012
    - American Physical Therapy Association, San Diego, CA, January 21-24, 2013.

  - International Society of Prosthetics and Orthotics, Hyderabad, India, February 4-7, 2013.
- Papers
  - One paper, "Method for evoking a trip response using a treadmill based perturbation during locomotion", has been submitted to the *Journal of Biomechanics*
  - Another paper, "Fall Prevention Training for Warfighters with Transtibial Amputations", has been invited for submission to *Clinical Orthopedics and Related Research.*
- Awards
  - Received **Best Poster Award** at the European Society of Movement Analysis for Adults and Children, Stockholm, Sweden, September 12-15, 2012.

Conclusion

We have designed and developed a demonstrably effective, clinically relevant and scientifically based method for increasing and accelerating the progressive adaptation of warfighters with a lower extremity amputation to their prosthesis. This rehabilitation method uses a novel and innovative treadmill training method. The training method is aimed at increasing the ability for amputees to rely on their prostheses, particularly in a challenging environment, and thus, improve their functional capabilities. Based on the results obtained to date, warfighters with unilateral amputations have reduced falls and retained their improved skills for at least six months following training.

In order to test the outcomes in a repeatable and reliable manner, we have also developed a test protocol on the CAREN which allows us to cause postural perturbations which result in falls in untrained individuals. This protocol will have utility in assessing other interventions aimed at improving the gait and stability of warfighters with lower extremity amputations.

Future work should expand this research program to warfighters with bilateral lower extremity amputations. The current program is only enrolling subjects with unilateral amputations. This enrollment criterion was used to validate the method on individuals who are not as mobility challenged. Further, when the program was conceived, there was not the preponderance of bilateral lower extremity amputees. Given the success of the current program, advancing the training to individuals with bilateral lower extremity amputations is now warranted.